Part VI: Summary of the risk management plan

This is a summary of the risk management plan (RMP) for Xylodex/Klaridex. The RMP details important risks of Xylodex/Klaridex how these risks can be minimised, and how more information will be obtained about Xylodex/Klaridex's risks and uncertainties (missing information).

Xylodex/Klaridex´s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Xylodex/Klaridex should be used.

I. The medicine and what it is used for

Xylodex/Klaridex is authorised for use in short-term treatment of nasal congestion in connection with common cold and to support the treatment of cutaneous and mucosal wound healing, for relief of vasomotor rhinitis (runny nose) and for the treatment of impaired nasal respiration after nasal surgery (see SmPC for the full indication). It contains xylometazolin hydrochloride and dexpanthenol as the active substances and it is given as nasal spray in solution.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Xylodex/Klaridex, together with measures to minimise such risks and the proposed studies for learning more about Xylodex/Klaridex 's risks, are outlined below.

- Product information including warnings, precautions, and advice on correct use. Package leaflet is enclosed in the package and the Summary of Product Characteristics (and Package Leaflet) are published on the webpage of the involved Medicines Agencies (NO, DK, SE).

These measures constitute *routine risk minimisation* measures.

II.A List of important risks and missing information

Important risks of Xylodex/Klaridex are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Xylodex/Klarigenle based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	Xylodex/Klaridex may cause must not be used if in intraocular pressure, especially narrow angle glaucoma.
	Xylodex/Klaridex may cause irregular heartbeat
Important potential risks	Xylodex/Klaridex may cause hypertension following concomitant use of MAO-inhibitors
Missing information	There are insufficient information about the use og Xylodex/Klaridex in pregnancy and lactation and therefore the product should not be

List of important risks and missing information	
	used.

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Xylodex/Klaridex.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Xylodex/Klaridex